K031872

JUN 2 0 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

General Information

A. Submitted By:

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B. Device Trade Name: Ultra-High Energy General Purpose Collimator [for cardiac imaging]

Models: Ultra-High Energy General Purpose Collimator (UHGP)

Common Name: Collimator

Classification Name: 511 keV Ultra-High Energy Collimator (UHEC) for SPECT (21CFR 892.1200)

Device Class: 21CFR 892.1200, Class II

Product Code: 90 KPS

C. Date prepared: June 3, 2003

D. Predicate Device: UHE Collimator (Option to the PRISM 3000 Gamma Camera System) K963406

E. Intended Use:

The Ultra-High Energy General Purpose Collimator (UHGP) is intended to be used to detect and image the distribution of high-energy photons from an administered positron-emitting radioactive agent in the human body, specifically cardiac imaging. The Ultra-High Energy General Purpose Collimator (UHGP) will be used on the dual detector Forte Gamma Camera (K982911) and on the dual detector Vertex Gamma Camera (K922080).

F. Device Description:

The Ultra-High Energy General Purpose Collimator (UHGP) is an optional device for the Forte™ and Vertex™ gamma camera systems, similar to conventional low energy collimators. It was developed to collimate the gamma rays emitted perpendicularly from a patient to a gamma ray detector, so that a proper image can be formed. This design concept is essentially the same as other conventional lower energy collimators used in Nuclear Medicine clinics, except that the current device is intended for ultra-high energy (511 keV) radiopharmaceuticals. Hence, the focus of the design elements are 1) proper hole size and thickness to provide proper spatial resolution and sensitivity for clinical use and 2) a proper mechanical mechanism to ensure safety.

The UHGP collimator consists of three major components: the collimation core, collimator frame, and collimator cover. The weight of this collimator is 300 pounds. The detailed parameters are shown on the following page in Table 4-1. The collimator core is made of lead. The hole size, the septal length, and septal thickness are 2.7, 60 and 2.3 mm, respectively. The collimator frame is used to support the core and connect to the detector buckets. For the Forte and Vertex systems, the frame and core size are the same as shown by the specification for the imaging Field of View (FOV). See the table below. The collimator cover is used to prevent direct patient contact with the lead core. More importantly, it has a collision sensor to prevent any unexpected detector motion resulting in collimator contact with patient, including un-intended detector radius move-in by operators.

Similar to other conventional low energy collimators, the UHGP collimator can be stored in a standard collimator storage device shipped with the base camera. The collimator storage devices are different for different base cameras (as shown in Figures 3 and 5), but all of the storage designs take the dimensions and mechanical strength of the UHGP into consideration.

The collimator exchange is done either manually as in the case of the Vertex manual camera , or semi-automatically as in case of the Forte camera and the Vertex auto camera. In all cases, the operator needs to activate the pre-programmed exchange motion program. The program will prompt the operator to proceed through the steps necessary for the exchange. In addition, the pre-programmed program will provide pre-cautionary warnings to the operator during the critical steps for safety precaution. These exchange procedures are the same as in the case of conventional collimator exchange.

The mechanical design of the gantry for the above named camera systems, Forte and Vertex, was reviewed for strength, deflection and motion control. It was deemed that these systems are capable of supporting the weights of collimators specified. A separate risk assessment is provided in Section 9.

The detector bucket in each of the above named cameras has the same design, and the detector bucket in each camera is well shielded against 511 kev. The shielding thickness varies from 0.9" close to the front of PMT tubes to 0.7" close to the back of PMT tubes. This provides enough shielding from both the random activity caused by other patients walking through the hall way and the scatter activity from the patient himself.

The UHGP collimator has two mechanisms to safeguard patients. The first one is the collimator collision sensor. It will halt any camera motion when the collimator surface is subjected to a pressure of 2 – 2.75 psi. The second safeguard is the fail-safe latching mechanism that locks the collimator all the time, unless it is activated intentionally by the operator. There is no additional software development for UHGP collimator itself. The pre-programmed collimator exchange program in the Forte camera and the Vertex camera is the exactly the same program used for the conventional collimator. Additionally, there is no new processing/display software for this collimator. Any processing and display software, which is used for other conventional collimators, can be used by trained medical professionals with their discretion.

G. Comparison to Predicate Device:

Since collimators are very straightforward devices, the key performance index of the devices are the resolution, sensitivity, and mechanical safety. The current device provides a better resolution than the predicate device. This, in turn, will improve the image quality. However, the sensitivity for the current device is lower than the predicate device due to the better resolution. It is 174 cpm/uCi. But, this is very comparable to the low energy collimators. Hence, it is deemed adequate from the sensitivity point of view.

The table on the following page shows the specifications of the Picker UHE – the predicate device – compared to the UHGP. For comparison, a conventional collimator, HEGP – High Energy General Purpose, is also listed in the table. One item to note is the weight of the HEGP: it is heavier than the Picker Predicate Device.

Comparison To Predicate Device

Specifications	This application (Current device) UHGP Collimator For use on the Forte Gamma Camera and the Vertex Gamma Camera	Predicate device Picker UHE collimator Triple head camera K963406
intrinsic resolution=	<3.5	3.9
Septal length (mm)=	60	77
hole size(mm)=	2.7	5.08
sep. thickness(mm)=	2.3	3.43
Weights/per collimator	300 lbs	220 lbs
Collimation per camera	2	3
Imaging FOV	20x15"	20x15"
Latching mechanism	Software control	Software control
Bucket shielding	0.7 –0.9"	Unknown
Planar Resolution: Distance (cm)	Resolution	Resolution
0	<=6.0 mm	7.01
5	<=8.0 mm	10.65
10	<=10.0 mm	14.53
15	<=14.5 mm	18.50
20	<=17.0 mm	22.51
sensitivity (cpm/μCi) – 511keV	<174	435
Septal penetration(%)	4.6	3.5

H. System Performance Test:

The Ultra-High Energy General Purpose Collimator (UHGP) performance was measured according to the NEMA NU1: Performance Measurements of Scintillation Cameras (1994). Clinical images were also examined.

In addition, a Verification Test was performed to test the functionality, as well as Risk Assessment and Stress Analysis were performed.

I. Conclusion:

The Ultra-High Energy General Purpose Collimator (UHGP) [for cardiac imaging] is substantially equivalent to the predicate device based upon similar intended use, technological comparison, and system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2003

ADAC Laboratories
% Mr. Morten Christensen
Office Coordinator, 510(k) Review
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K031872
Trade/Device Name: Ultra-High Energy General Purpose Collimator (UHGP) [for cardiac imaging]
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: June 13, 2003
Received: June 17, 2003

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) NUMBER (IF KNOWN): K031872

DEVICE NAME: The Ultra-High Energy General Purpose Collimator (UHGP) [for cardiac imaging]

SPONSOR NAME: ADAC Laboratories

Nuclear Medicine Device

Indications For Use:

To detect and image the distribution of high-energy photons from an administered positron-emitting radioactive agent (radionuclides) in the human body, specifically cardiac imaging. The Ultra-High Energy General Purpose Collimator (UHGP) will be used on the dual detector Forte Gamma Camera (K982911) and on the dual detector Vertex Gamma Camera (K922080).

	Technique	Yes	Imaging method	Energy Range (keV)
A.	Planar Cardiac Imaging	X	Positron imaging without coincidence	511 keV emitters
B.	SPECT Cardiac Imaging	X	Positron imaging without coincidence	511 keV emitters

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use_____ (Optional Format 1-2-96)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031872